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EXAMINER	
SOUAYA, JEHANNE E	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/741,664	RASHTCHIAN ET AL.	
	Examiner	Art Unit	
	Jehanne E Souaya	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-31 and 33-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-31 and 33-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8/2002* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Currently, claims 1-3, 5-31, and 33-59 are pending in the instant application. Claims 48-59 are newly added. Claims 4 and 32 have been cancelled. The previous restriction requirement is withdrawn in view of the claims having been searched in a parent application. Therefore, an action on the merits of claims 1-3, 5-31, and 33-59 follows. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections that have not been reiterated from the previous office action are hereby withdrawn in view of the amendment to the claims to include the limitation "contains no nucleic acid molecules". It is noted however, that such limitation has been rejected under 112/1st paragraph and that such rejections would be reapplied to the claims (including any claims dependent therefrom and encompassed by the references) upon the cancellation of the new matter, and that such would not affect the finality of any subsequent office action. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow (from response dated Aug 22, 2002), where applicable. This action is NON-FINAL.

Priority

2. It is noted that claims 34 and 36 receive priority back to the '720 application as the subject matter was first disclosed in said application. Therefore, the effective filing date of such claims is 2/14/1997.

New Grounds of Objection and Rejection

Claim Objections

3. Claims 40-43 are improperly dependent from claims 33 or 34 because these claims fail the infringement test. See MPEP 608.01(n). For example, the product of claim 40 can be separately infringed from the method of claim 33.

Specification

4. The amendment filed 8/22/2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the claims have been amended to recite the limitation "wherein the composition [kit] contains no nucleic acid molecules. This negative recitation does not find support in the instant specification. MPEP section 2173.05 (i) states:

> Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff 'd mem., 738 F.2d 453 (Fed. Cir. 1984). **The mere absence of a positive recitation is not basis for an exclusion**. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

In the instant case, the formulations in table 1 do not list concentration of nucleic acid molecules, however, as stated in the MPEP "The mere absence of a positive recitation is not basis for an exclusion." The instant formulations were used in examples of PCR and nucleic acid

sequencing, which illustrate compositions that do and would be expected by one of skill in the art to contain nucleic acid molecules.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3, 5-31 and 33-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This a New Matter rejection.

The claims have been amended to add the negative limitation "wherein the composition [kit] contains no nucleic acids". This negative recitation does not find support in the instant specification. MPEP section 2173.05 (i) states:

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff 'd mem., 738 F.2d 453 (Fed. Cir. 1984). **The mere absence of a positive recitation is not basis for an exclusion**. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

In the instant case, the formulations in table 1 do not list concentration of nucleic acid molecules, however, as stated in the MPEP "The mere absence of a positive recitation is not basis for an exclusion." The instant formulations were used in examples of PCR and nucleic acid sequencing, which illustrate compositions that do and would be expected by one of skill in the art to contain nucleic acid molecules.

7. Claims 5-23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to compositions generally comprising any mutant DNA polymerase of Taq, Tne, Tma, Pfu, Pwo, VENT, and DEEPVENT. These compositions comprise an extremely large number of mutant DNA polymerases, which the specification does not describe, and also includes mutant polymerases that have not been taught in either the specification *or* the art. The mere recitation that mutant DNA polymerases are part of the invention is not a description of the mutant polymerases themselves and is not representative of the large number genus of polymerases encompassed by the claims. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See

page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed mutant polymerases, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 40, 44, 48, and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Scalice et al (hereinafter referred to as Scalice; US Patent 5,338,671).

Scalice teaches a composition containing Taq DNA polymerase (50 U/mL), Tris buffer with MgCl, Nonidet P-40 nonionic surfactant, Tween (53-54), and an antibody (claim 44) which binds to Taq polymerase (see col. 15, lines 42-55). Scalice also inherently teaches the limitation recited in claim 48 that the composition is stable upon storage as the composition of Scalice is the same as that of the instant claims and therefore the compositions have the same characteristics. Further, the composition taught by Scalice must be stable upon storage for some length of time because it is stable under the cycling temperatures of the PCR reaction such that the polymerase retains activity and the reagents are stable to allow amplification of a target nucleic acid.

With regard to claim 40, the claim is drawn to a nucleic acid molecule amplified by the method of claim 33. Scalice teaches a nucleic acid amplified by PCR. It is noted that claim is a product by process claim. Where the claimed and prior art products are identical or substantially identical (in the instant case, the claim is drawn any nucleic acid molecule and the prior art teaches a nucleic acid molecule) in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433, (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the application and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant case, the molecules are structurally the

same and the nucleic acid molecule of claim 40 is not altered structurally by the method of making it.

Response to Arguments

The response traverses the rejection. The response asserts that Scalice does not teach a composition that doesn't contain nucleic acids. This argument was not found persuasive as Scalice does teach a composition that comprises a thermostable DNA polymerase, a buffer salt containing magnesium, and an antibody which specifically binds to the thermostable DNA polymerase but that contains no nucleic acid molecules (col. 15, lines 47-55).

10. Claims 34 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Sorge et al (hereinafter referred to as Sorge; WO 95/16028)

Sorge teaches a composition for amplification and a kit containing this composition, comprising a mixture of a 3' exonuclease (+) DNA polymerase, particularly Taq polymerase, and a 3' exo (-) DNA polymerase, specifically Pfu, with dNTPs (200 μM) and salt buffer containing magnesium (see pages 22-23, 26) and triton X-100 (see table 17). Sorge teaches ratios of Taq to Pfu of 9:1, 7:3, 5:5, 3:7, and 1:9 in the composition and teaches the use of this composition in an amplification reaction comprising contacting the composition to a target nucleic acid to be amplified. Sorge teaches that all ratios of the two polymerases achieved amplification.

With regard to claim 40, the claim is drawn to a nucleic acid molecule amplified by the method of claim 33. Sorge teaches a nucleic acid amplified by PCR. It is noted that claim is a product by process claim. Where the claimed and prior art products are identical or substantially

identical (in the instant case, the claim is drawn any nucleic acid molecule and the prior art teaches a nucleic acid molecule) in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433, (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the application and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant case, the molecules are structurally the same and the nucleic acid molecule of claim 40 is not altered structurally by the method of making it.

11. Claims 1-3, 5, 8, 24-28, 30, 31, 35, and 48-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Vizard et al (hereinafter referred to as Vizard, previously referred to as "Kodak PCT"; WO 9008839).

Vizard teaches a composition for use in nucleic acid sequencing which contains a thermostable polymerase (Taq) at from 100-500 U/mL, a salt buffer which includes a magnesium salt, dNTPs (up to 150 μM; the recitation of "about 200-about 300 μM" is broadly interpreted to encompass 150μM), ddNTPs, and non ionic detergents such Triton X-100 (see p 3-5). Vizard specifically teaches that these compositions do not contain nucleic acids and are generated to simply add DNA to the solution, which eliminates many steps (ie, adding each component every time a reaction is carried out) and is far more amenable to automation (see page 6). Vizard teaches packaging such composition in kit format (p. 10, 19), without the need for dilution steps for convenience to the user. Vizard inherently teaches the limitation recited in claims 24 and 25 that the polymerase retains 90% activity for at least 4 weeks when stored at 20 or 25 C and for at

least a year when stored at 4C because the composition of the claims and the composition of Vizard are the same and therefore the compositions have the same characteristics. Vizard also inherently teaches the limitation recited in claims 48 and 49 that the composition is stable upon storage as the composition of Vizard are the same as that of the instant claims and therefore the compositions have the same characteristics. Further, Vizard teaches that the composition is stable on storage (p. 7).

Response to Arguments

The response traverses the rejection. The response asserts that Vizard does not teach a composition comprising a mixture of reagents at working concentrations because Vizard teaches that the reaction is a "concentrate", and that the concentrate has to be significantly diluted before use. This argument has been thoroughly reviewed but was not found persuasive. Firstly, the term "working concentration" is very broad and could encompass concentrations of components relative to each other. That is, this term could encompass that the components are present in concentrations that can "work" relative to the other components. The claimed recitation of "working concentration" does not and cannot exclude dilution of the whole compositions or compositions in kits, because they are claimed to be used (dependent method claims) in reactions that will require the presence of additional reagents (primers, template DNA, etc). Such inherently requires that the term "working concentration" in the claim cannot exclude dilution. It is further noted, that the concentrations of the reagents in the composition of Vizard are present in concentrations that can be used in sequencing and PCR reactions. In addition, as the components of Vizard are present in the same concentrations as that of the instantly pending

claims, Vizard inherently teaches components at "working concentration" because the concentration of the components in the instant claims and that of Vizard are the same.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vizard in view of Soderlund et al (hereinafter referred to as Soderlund; EP 0648280).

Vizard teaches a composition for use in nucleic acid sequencing which contains a thermostable polymerase (Taq) at from 100-500 U/mL, a salt buffer which includes a magnesium salt, dNTPs (up to 150 μM; the recitation of "about 200-about 300 μM" is broadly interpreted to encompass 150μM), ddNTPs, and non ionic detergents such Triton X-100 (see p 3-5). Vizard

specifically teaches that these compositions do not contain nucleic acids and are generated to simply add DNA to the solution, which eliminates many steps (ie, adding each component every time a reaction is carried out) and is far more amenable to automation (see page 6). Vizard teaches packaging such composition in kit format (p. 10, 19), without the need for dilution steps for convenience to the user.

Vizard does not teach concentrations of ddNTPs at concentrations of about .08-about 5 μM. However, Soderlund demonstrates sequencing of DNA in primer extension reactions where the concentration of ddNTPs is about 1 μM. Therefore, it would have bee prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Vizard in view of Soderlund to include compositions wherein the ddNTPs were present at 1 μM as taught by Soderlund for the expected advantage of using an effective amount of ddNTPs to achieve sequencing, in for example, a primer extension reaction, without wasting unnecessary extra ddNTPs. The ordinary artisan would have been motivated to determine the concentration of ddNTPs needed to carry out effective sequencing for the purposes of not wasting reagents. As stated in the MPEP (2144.05),

"Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")".

Further, as Soderlund teaches sequencing in primer extension reactions, for example, can be achieved with 1 μM ddNTPs, the ordinary artisan would have had a reasonable expectation of success that sequencing reactions could function at such concentration.

15. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorge in view of Slatko (Molecular Biotechnology, vol. 6, 1996; pp 311-322).

Sorge teaches a method for nucleic acid amplification by PCR comprising contacting a nucleic acid with a mixture of a 3' exonuclease (+) DNA polymerase, particularly Taq polymerase, and a 3' exo (-) DNA polymerase, specifically Pfu, with dNTPs (200 μM) and salt buffer containing magnesium (see pages 22-23, 26) and triton X-100 (see table 17). Sorge teaches ratios of Taq to Pfu of 9:1, 7:3, 5:5, 3:7, and 1:9 in the composition and teaches the use of this composition in an amplification reaction comprising contacting the composition to a target nucleic acid to be amplified. Sorge teaches that all ratios of the two polymerases achieved amplification. The DNA polymerases were at a total concentration of 2.5 Units per 100 μL. Sorge teaches that the advantage of using the two polymerases is to reduce the number of mismatch errors that can occur with the thermostable polymerases.

Sorge does not specifically teach using this composition for nucleic acid sequencing. However Slatko teaches a method for nucleic acid thermal cycle dideoxy sequencing which uses a composition containing a thermostable polymerase such as Taq, VENT, Taq derivatives, DEEP VENT exo-, Pfu exo-, in a salt buffer containing MgCl, a non ionic surfactant, deoxynucleotides, and dideoxynucleotides (page 311). Slatko teaches that this sequencing method is a modification

of dideoxynucleotide sequencing which incorporates the advantages of PCR amplification using thermostable polymerases to extend a primer by polymerization.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention as made to have applied the composition taught by Sorge to the thermal DNA sequencing method of Slatko in order to make the invention as a whole and to achieve the expected benefit of improving the fidelity of the sequencing reaction of Slatko to overcome the misincorporation problems associated with the error prone exo-thermostable polymerases as taught by Sorge.

16. Claims 1-2, 5, 6, 8-9, 18, 19, 24-28, 30, 33, 40, 48, 49, and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg et al (hereinafter referred to as Lundberg; Gene, vol. 108, pp 1-6; 1991) in view of Sobol et al (hereinafter referred to as Sobol; US Patent 5,543,296) and Isner (US Patent 5,652,225) and Vizard.

Lundberg teaches a composition for nucleic acid amplification comprising either Taq (claims 8-9) or Pfu DNA polymerase at 25 U/mL (claims 18-19), a salt buffer containing magnesium (claim 26), dNTPs at a concentration of 200 μM (claim 28)) and triton X-100 (claims 27 and 53-55) (see page 4, cols 1-2). "About 20 units/mL" of polymerase is interpreted to encompass 25 U/mL (instant claims 9 and 19). Lundberg teaches that the reactions were used in PCR to amplify nucleic acids (claims 33 and 40).

Lundberg does not specifically teach a composition or kit comprising a composition wherein the composition does not contain any nucleic acid molecules. However, Sobol discloses the use of master mixes of reagents while preparing multiple samples for PCR (see col. 17, lines

19-44), wherein the master mix includes all PCR reagents, including polymerase, other than primers and template. It is well known to those of skill in the art that a master mix is typically employed when performing multiple PCR reactions, in order to improve efficiency. For example, Isner discloses the use of master mixes in the preparation of enzymatic reactions mixtures results in "greater accuracy and reproducibility (see col. 15, lines 37-39). Also, Vizard teaches making master mix compositions and kits comprising such compositions that contain all reagents necessary for nucleic acid sequencing, including polymerase, other than DNA template. Vizard specifically teaches that these compositions do not contain nucleic acids and are generated to simply add DNA to the solution, which eliminates many steps (ie, adding each component every time a reaction is carried out) and is far more amenable to automation (see page 6). Vizard teaches packaging such composition in kit format (p. 10, 19), without the need for dilution steps for convenience to the user. In view of the teachings of Sobol, Isner, and Vizard, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have prepared the PCR reaction mixtures of Lundberg by first preparing a master mix composition including all reagents other than primers and template. The ordinary artisan would have been motivated to have made such a modification for the expected advantage of improving the efficiency, accuracy, and reproducibility in conducting PCR amplification. The ordinary artisan would have been motivated to prepare such master mixes at "working concentrations" in order to have reaction mixtures that required only the addition of template and primers to improve the efficiency of performing multiple amplification reactions. Further, the ordinary artisan would have been motivated to have prepared a master mix including all the reagents except for primers and template in order to have possessed a single master mix

composition that could be successfully employed with a variety of different templates and primers, and thus could be used in any amplification reaction.

With regard to claims 48 and 49, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Lundberg in view of Sobol, Isner and Vizard is the same as the instantly claimed composition, such are considered to have the same properties and characteristics. Further, the composition taught by Lundberg in view of Sobol, Isner, and Vizard must be stable upon storage for some length of time because it is stable under the cycling temperatures of the PCR reaction such that the polymerase retains activity and the reagents are stable to allow amplification of a target nucleic acid. With regard to claims 24 and 25, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Lundberg in view of Sobol, Isner, and Vizard is the same as the instantly claimed composition, such are considered to have the same properties.

17. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg in view of Sobol, Isner, and Vizard as applied to claims 1-2, 5, 6, 8, 9, 18, 19, 24-28, 30, 33, 40, 48-49, and 53-55 above, and further in view of Hughes et al (hereinafter referred to as Hughes, WO 96/10640).

The teachings of Lundberg in view of Sobol, Isner, and Vizard are set forth above. Lundberg in view of Sobol, Isner, and Vizard do not teach using Tne DNA polymerase. However, Hughes teaches the use of Tne thermostable DNA polymerase, and mutants of such, in DNA amplification and sequencing reactions. Furthermore, Hughes teaches kits which comprise the Tne polymerase, dNTPs, and ddNTPs and no nucleic acid molecules. Therefore, it would

have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of Lundberg in view of Sobol, Isner and Vizard to include compositions that contained Tne polymerase as Hughes teaches that such polymerase is useful in DNA amplification and sequencing reactions.

18. Claims 1-2, 5, 6, 8-11, 18, 19, 24-28, 30, 33, 40, 48, 49, and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes in view of Lundberg , Sobol , Isner, Vizard.

Hughes teaches the use of Tne thermostable DNA polymerase, and mutants of such, in DNA amplification and sequencing reactions. Furthermore, Hughes teaches kits which comprise the Tne polymerase, dNTPs, and ddNTPs and no nucleic acid molecules.

Hughes does not teach a composition that contains a mixture of polymerase, dNTPs, and ddNTPs, and contains no nucleic molecules, however, However, Sobol discloses the use of master mixes of reagents while preparing multiple samples for PCR (see col. 17, lines 19-44), wherein the master mix includes all PCR reagents, including polymerase, other than primers and template. It is well known to those of skill in the art that a master mix is typically employed when performing multiple PCR reactions, in order to improve efficiency. For example, Isner discloses the use of master mixes in the preparation of enzymatic reactions mixtures results in "greater accuracy and reproducibility (see col. 15, lines 37-39). Also, Vizard teaches making master mix compositions and kits comprising such compositions that contain all reagents necessary for nucleic acid sequencing, including polymerase, other than DNA template. Vizard specifically teaches that these compositions do not contain nucleic acids and are generated to simply add DNA to the solution, which eliminates many steps (ie, adding each component every

time a reaction is carried out) and is far more amenable to automation (see page 6). Vizard teaches packaging such composition in kit format (p. 10, 19), without the need for dilution steps for convenience to the user. In view of the teachings of Sobol, Isner, and Vizard, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have improved the PCR or sequencing kit Hughes by included a premixed composition that contains polymerase, dNTPs, and optionally ddNTPs for the obvious improvement of providing the user with a premixed solution that would require less steps (mixing the components of the kit of Hughes, together) in carrying out the method. Furthermore, the ordinary artisan would have been motivated to have made such a modification for the expected advantage of improving the efficiency, accuracy, and reproducibility in conducting PCR amplification. The ordinary artisan would have been motivated to prepare such master mixes at "working concentrations" in order to have reaction mixtures that required only the addition of template and primers to improve the efficiency of performing multiple amplification reactions. Lundberg demonstrates concentrations of reagents for PCR, and Vizard demonstrates concentrations of reagents for sequencing

With regard to claims 48 and 49, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Hughes in view of Sobol, Isner, Vizard and Lundberg is the same as the instantly claimed composition, such are considered to have the same properties and characteristics. With regard to claims 24 and 25, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Hughes in view of Sobol, Isner, Vizard, and Lundberg is the same as the instantly claimed composition, such are considered to have the same properties.

19. Claims 2, 5, 6, 8, 18, 24-28, 30, 33, 45-47, 49, 51, and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scalice in view of Sobol, Isner, and Vizard.

Scalice teaches a composition containing Taq DNA polymerase (50 U/mL) (instant claims 8, 18), Tris buffer with MgCl (instant claim 26), Nonidet P-40 nonionic surfactant, Tween (instant claims 27, 53-57), dNTPs (200 μM) (instant claim 28), and an antibody (claims 44-47) which binds to Taq polymerase (see col. 15, lines 42-65). Scalice specifically teaches packaging reagents in a kit (col 3, lines 15-30; instant claim 30) and teaches PCR reactions (col. 3, lines 32-50; instant claim 34) for amplification of target DNA (examples 1 and 2; instant claim 40). Scalice further teaches using different thermostable polymerases such as Pfu (col. 7, lines 7-11; instant claim 6).

Scalice does not specifically teach a composition or kit comprising a composition wherein the composition does not contain any nucleic acid molecules. However, Sobol discloses the use of master mixes of reagents while preparing multiple samples for PCR (see col. 17, lines 19-44), wherein the master mix includes all PCR reagents, including polymerase, other than primers and template. It is well known to those of skill in the art that a master mix is typically employed when performing multiple PCR reactions, in order to improve efficiency. For example, Isner discloses the use of master mixes in the preparation of enzymatic reactions mixtures results in "greater accuracy and reproducibility (see col. 15, lines 37-39). Also, Vizard teaches making master mix compositions and kits comprising such compositions that contain all reagents necessary for nucleic acid sequencing, including polymerase, other than DNA template. Vizard specifically teaches that these compositions do not contain nucleic acids and are generated to simply add DNA to the solution, which eliminates many steps (ie, adding each

component every time a reaction is carried out) and is far more amenable to automation (see page 6). Vizard teaches packaging such composition in kit format (p. 10, 19), without the need for dilution steps for convenience to the user. In view of the teachings of Sobol, Isner, and Vizard, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have prepared the PCR reaction mixtures of Scalice by first preparing a master mix composition including all reagents other than primers and template. The ordinary artisan would have been motivated to have made such a modification for the expected advantage of improving the efficiency, accuracy, and reproducibility in conducting PCR amplification. The ordinary artisan would have been motivated to prepare such master mixes at "working concentrations" in order to have reaction mixtures that required only the addition of template and primers to improve the efficiency of performing multiple amplification reactions. Further, the ordinary artisan would have been motivated to have prepared a master mix including all the reagents except for primers and template in order to have possessed a single master mix composition that could be successfully employed with a variety of different templates and primers, and thus could be used in any amplification reaction.

With regard to claims 48 and 49, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Scalice in view of Sobol, Isner and Vizard is the same as the instantly claimed composition, such are considered to have the same properties and characteristics. Further, the composition taught by Scalice in view of Sobol, Isner, and Vizard must be stable upon storage for some length of time because it is stable under the cycling temperatures of the PCR reaction such that the polymerase retains activity and the reagents are stable to allow amplification of a target nucleic acid. With regard to claims 24 and

25, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Scalice in view of Sobol, Isner, and Vizard is the same as the instantly claimed composition, such are considered to have the same properties.

20. Claims 1, 2, 5-9, 14-19, 22-26, 28, 33, 37-43, and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnes et al (hereinafter referred to as Barnes; PNAS, vol. 91, pp 2216-2220, 1994) in view of Sobol, Isner, and Vizard.

Barnes teaches a stable composition for nucleic acid amplification comprising a mutant form of Taq, Klentaql, which is exonuclease free and Pfu DNA polymerase, a salt buffer which contains magnesium and 250 μM dNTPs (page 2217, col. 1, para 2). Barnes also teaches compositions containing VENT and DEEP VENT DNA polymerases in combination with a Taq polymerase (page 2218, col. 2). Barnes teaches that this composition was used to amplify long nucleic acids (claims 33 and 40) larger than 8 kb (claims 37-39 and 41-43).

Barnes does not specifically teach a composition or kit comprising a composition wherein the composition does not contain any nucleic acid molecules. However, Sobol discloses the use of master mixes of reagents while preparing multiple samples for PCR (see col. 17, lines 19-44), wherein the master mix includes all PCR reagents, including polymerase, other than primers and template. It is well known to those of skill in the art that a master mix is typically employed when performing multiple PCR reactions, in order to improve efficiency. For example, Isner discloses the use of master mixes in the preparation of enzymatic reactions mixtures results in "greater accuracy and reproducibility (see col. 15, lines 37-39). Also, Vizard teaches making master mix compositions and kits comprising such compositions that contain all reagents

necessary for nucleic acid sequencing, including polymerase, other than DNA template. Vizard specifically teaches that these compositions do not contain nucleic acids and are generated to simply add DNA to the solution, which eliminates many steps (ie, adding each component every time a reaction is carried out) and is far more amenable to automation (see page 6). Vizard teaches packaging such composition in kit format (p. 10, 19), without the need for dilution steps for convenience to the user. In view of the teachings of Sobol, Isner, and Vizard, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have prepared the PCR reaction mixtures of Barnes by first preparing a master mix composition including all reagents other than primers and template. The ordinary artisan would have been motivated to have made such a modification for the expected advantage of improving the efficiency, accuracy, and reproducibility in conducting PCR amplification. The ordinary artisan would have been motivated to prepare such master mixes at "working concentrations" in order to have reaction mixtures that required only the addition of template and primers to improve the efficiency of performing multiple amplification reactions. Further, the ordinary artisan would have been motivated to have prepared a master mix including all the reagents except for primers and template in order to have possessed a single master mix composition that could be successfully employed with a variety of different templates and primers, and thus could be used in any amplification reaction.

With regard to claims 48 and 49, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Barnes in view of Sobol, Isner and Vizard is the same as the instantly claimed composition, such are considered to have the same properties and characteristics. Further, the composition taught by Barnes in view of Sobol, Isner,

and Vizard must be stable upon storage for some length of time because it is stable under the cycling temperatures of the PCR reaction such that the polymerase retains activity and the reagents are stable to allow amplification of a target nucleic acid. With regard to claims 24 and 25, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Barnes in view of Sobol, Isner, and Vizard is the same as the instantly claimed composition, such are considered to have the same properties.

21. Claims 1, 2, 5, 12, 13, 24-26, 33, 40, and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelfand et al (hereinafter referred to as Gelfand; US Patent 5,420,029) in view of Sobol, Isner, and Vizard.

Gelfand teaches a stable composition for nucleic acid amplification comprising 25 U/mL of Tma polymerase, a salt buffer containing magnesium and 200 μM dNTPs which was used to amplify template nucleic acid.

Gelfand does not specifically teach a composition or kit comprising a composition wherein the composition does not contain any nucleic acid molecules. However, Sobol discloses the use of master mixes of reagents while preparing multiple samples for PCR (see col. 17, lines 19-44), wherein the master mix includes all PCR reagents, including polymerase, other than primers and template. It is well known to those of skill in the art that a master mix is typically employed when performing multiple PCR reactions, in order to improve efficiency. For example, Isner discloses the use of master mixes in the preparation of enzymatic reactions mixtures results in "greater accuracy and reproducibility (see col. 15, lines 37-39). Also, Vizard teaches making master mix compositions and kits comprising such compositions that contain all

reagents necessary for nucleic acid sequencing, including polymerase, other than DNA template. Vizard specifically teaches that these compositions do not contain nucleic acids and are generated to simply add DNA to the solution, which eliminates many steps (ie, adding each component every time a reaction is carried out) and is far more amenable to automation (see page 6). Vizard teaches packaging such composition in kit format (p. 10, 19), without the need for dilution steps for convenience to the user. In view of the teachings of Sobol, Isner, and Vizard, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have prepared the PCR reaction mixtures of Gelfand by first preparing a master mix composition including all reagents other than primers and template. The ordinary artisan would have been motivated to have made such a modification for the expected advantage of improving the efficiency, accuracy, and reproducibility in conducting PCR amplification. The ordinary artisan would have been motivated to prepare such master mixes at "working concentrations" in order to have reaction mixtures that required only the addition of template and primers to improve the efficiency of performing multiple amplification reactions. Further, the ordinary artisan would have been motivated to have prepared a master mix including all the reagents except for primers and template in order to have possessed a single master mix composition that could be successfully employed with a variety of different templates and primers, and thus could be used in any amplification reaction.

With regard to claims 48 and 49, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Gelfand in view of Sobol, Isner and Vizard is the same as the instantly claimed composition, such are considered to have the same properties and characteristics. Further, the composition taught by Gelfand in view of Sobol,

Isner, and Vizard must be stable upon storage for some length of time because it is stable under the cycling temperatures of the PCR reaction such that the polymerase retains activity and the reagents are stable to allow amplification of a target nucleic acid. With regard to claims 24 and 25, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Gelfand in view of Sobol, Isner, and Vizard is the same as the instantly claimed composition, such are considered to have the same properties.

22. Claims 1, 2, 6, 20, 24-26, 28, 33, 40, and 48-49 rejected under 35 U.S.C. 103(a) as being unpatentable over Hinnisdaels et al (hereinafter referred to as Hinnisdaels, BIOTECHNIQUES, vol. 20, 1996, p 186, 188) in view of Sobol, Isner, and Vizard.

Hinnisdaels teaches a composition for amplification and a method for amplification containing Pwo Thermostable DNA polymerase, a salt buffer containing magnesium, 200 μM dNTP and about 100 μM polymerase (page 186, col. 3).

Hinnisdaels does not specifically teach a composition or kit comprising a composition wherein the composition does not contain any nucleic acid molecules. However, Sobol discloses the use of master mixes of reagents while preparing multiple samples for PCR (see col. 17, lines 19-44), wherein the master mix includes all PCR reagents, including polymerase, other than primers and template. It is well known to those of skill in the art that a master mix is typically employed when performing multiple PCR reactions, in order to improve efficiency. For example, Isner discloses the use of master mixes in the preparation of enzymatic reactions mixtures results in "greater accuracy and reproducibility (see col. 15, lines 37-39). Also, Vizard teaches making master mix compositions and kits comprising such compositions that contain all

reagents necessary for nucleic acid sequencing, including polymerase, other than DNA template. Vizard specifically teaches that these compositions do not contain nucleic acids and are generated to simply add DNA to the solution, which eliminates many steps (ie, adding each component every time a reaction is carried out) and is far more amenable to automation (see page 6). Vizard teaches packaging such composition in kit format (p. 10, 19), without the need for dilution steps for convenience to the user. In view of the teachings of Sobol, Isner, and Vizard, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have prepared the PCR reaction mixtures of Hinnisdaels by first preparing a master mix composition including all reagents other than primers and template. The ordinary artisan would have been motivated to have made such a modification for the expected advantage of improving the efficiency, accuracy, and reproducibility in conducting PCR amplification. The ordinary artisan would have been motivated to prepare such master mixes at "working concentrations" in order to have reaction mixtures that required only the addition of template and primers to improve the efficiency of performing multiple amplification reactions. Further, the ordinary artisan would have been motivated to have prepared a master mix including all the reagents except for primers and template in order to have possessed a single master mix composition that could be successfully employed with a variety of different templates and primers, and thus could be used in any amplification reaction.

With regard to claims 48 and 49, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Hinnisdaels in view of Sobol, Isner and Vizard is the same as the instantly claimed composition, such are considered to have the same properties and characteristics. Further, the composition taught by Hinnisdaels in view of Sobol,

Isner, and Vizard must be stable upon storage for some length of time because it is stable under the cycling temperatures of the PCR reaction such that the polymerase retains activity and the reagents are stable to allow amplification of a target nucleic acid. With regard to claims 24 and 25, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Hinnisdaels in view of Sobol, Isner, and Vizard is the same as the instantly claimed composition, such are considered to have the same properties.

23. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hinnisdaels in view of Sobol, Isner, and Vizard as applied to claims 1-2, 6, 20, 24-26, 28, 33, 40, and 48-49 above, and further in view of Lundberg.

The teachings of Hinnisdaels in view of Sobol, Isner, and Vizard are set forth above. Hinnisdaels in view of Sobol, Isner, and Vizard do not teach a composition comprising a Pwo polymerase wherein in the concentration of the polymerase is "about 20 units/milliliter". However, Lundberg demonstrates PCR amplification with polymerases at 25 units/mL. Therefore, it would have bee prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Hinnisdaels in view of Sobol, Isner, and Vizard to include compositions wherein the polymerase was 25 units/mL as taught by Lundberg for the expected advantage of using an effective amount of polymerase to achieve amplification, without wasting unnecessary extra polymerase. The ordinary artisan would have been motivated to determine the concentration of polymerase needed to carry out effective amplification for the purposes of not wasting enzyme. As stated in the MPEP (2144.05),

"Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum

or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")".

Further, as Lundberg teaches that amplification can be achieved with polymerases at 25 units/mL, the ordinary artisan would have had a reasonable expectation of success that the Pwo polymerase could function at such concentration in a method of amplification.

24. Claims 1, 2, 5, 8, 24-26, 28, 33, 40, 48, and 49 are rejected under 35 U.S.C. 103(a) as unpatentable Heath et al (hereinafter referred to as Heath; Nucleic Acids Research, vol 21, pp 5782-5785; 1993) in view of Sobol, Isner, and Vizard.

Heath teaches a stable composition for nucleic acid amplification comprising a mixture of Taq polymerase (a thermostable DNA polymerase), a salt buffer of Tris, KCL and MgCl and deoxynucleotides (page 5782, col. 2, para 2). The concentration of Taq polymerase was 0.5 U/μL which is 50 units/mL (claim 8) and the concentration of dNTPs was 200 μM (claim 28). Heath teaches that this composition was used in PCR reactions with template nucleic acid in order to amplify the nucleic acid (claims 33 and 40).

Heath does not specifically teach a composition or kit comprising a composition wherein the composition does not contain any nucleic acid molecules. However, Sobol discloses the use of master mixes of reagents while preparing multiple samples for PCR (see col. 17, lines 19-44), wherein the master mix includes all PCR reagents, including polymerase, other than primers and template. It is well known to those of skill in the art that a master mix is typically employed

when performing multiple PCR reactions, in order to improve efficiency. For example, Isner discloses the use of master mixes in the preparation of enzymatic reactions mixtures results in "greater accuracy and reproducibility (see col. 15, lines 37-39). Also, Vizard teaches making master mix compositions and kits comprising such compositions that contain all reagents necessary for nucleic acid sequencing, including polymerase, other than DNA template. Vizard specifically teaches that these compositions do not contain nucleic acids and are generated to simply add DNA to the solution, which eliminates many steps (ie, adding each component every time a reaction is carried out) and is far more amenable to automation (see page 6). Vizard teaches packaging such composition in kit format (p. 10, 19), without the need for dilution steps for convenience to the user. In view of the teachings of Sobol, Isner, and Vizard, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have prepared the PCR reaction mixtures of Heath by first preparing a master mix composition including all reagents other than primers and template. The ordinary artisan would have been motivated to have made such a modification for the expected advantage of improving the efficiency, accuracy, and reproducibility in conducting PCR amplification. The ordinary artisan would have been motivated to prepare such master mixes at "working concentrations" in order to have reaction mixtures that required only the addition of template and primers to improve the efficiency of performing multiple amplification reactions. Further, the ordinary artisan would have been motivated to have prepared a master mix including all the reagents except for primers and template in order to have possessed a single master mix composition that could be successfully employed with a variety of different templates and primers, and thus could be used in any amplification reaction.

With regard to claims 48 and 49, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Heath in view of Sobol, Isner and Vizard is the same as the instantly claimed composition, such are considered to have the same properties and characteristics. Further, the composition taught by Heath in view of Sobol, Isner, and Vizard must be stable upon storage for some length of time because it is stable under the cycling temperatures of the PCR reaction such that the polymerase retains activity and the reagents are stable to allow amplification of a target nucleic acid. With regard to claims 24 and 25, the claimed recitations are drawn to properties of the claimed composition. Since the composition taught by Heath in view of Sobol, Isner, and Vizard is the same as the instantly claimed composition, such are considered to have the same properties.

Conclusion

25. No claims are allowable over the cited prior art.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Primary Examiner
Art Unit 1634

10/31/03